

NOTICE OF PROPOSED REGULATION AMENDMENTS

California Code of Regulations

Title 17. – Public Health

Division 4 - California Institute For Regenerative Medicine

Chapter 5, Section 100500

Date: July 29, 2008

Deadline for Submission of Written Comment: September 22, 2008 – 5:00 p.m.

Public Hearing Date: September 22, 2008

Subject Matter of Proposed Amendments:

Grant Administration Policy for Academic and Non-Profit Institutions

Sections Affected: The proposed regulatory action amends the document incorporated by reference into Chapter 5, Section 100500, of Title 17 of the California Code of Regulations.

Authority: Article XXXV of the California Constitution and Health and Safety Code Section 125290.40, subdivision (j).

Reference: Sections 125290.30, 125290.35, 125290.40, 125290.45, 125290.50, 125290.60, 125290.70, 125292.10, Health and Safety Code.

Informative Digest/Policy Statement Overview:

The California Institute for Regenerative Medicine (“Institute” or “CIRM”) was established in 2005 after the passage in 2004 of Proposition 71 (the “Act”), the California Stem Cell Research and Cures Initiative. The statewide ballot measure established a new state agency to make grants and provide loans for stem cell research, research facilities and other vital research opportunities. The Independent Citizens’ Oversight Committee (“ICOC”) is the 29-member governing board for the Institute. The ICOC members are public officials, appointed on the basis of their experience earned in California's leading public universities, non-profit academic and research institutions, patient advocacy groups and the biotechnology industry. The Act charges the ICOC with developing standards and criteria to make grant awards and to develop standards and criteria for proper oversight of awards. (§ 125290.50.) To that end, CIRM adopted the CIRM Grants Administration Policy for Academic and Non-Profit Institutions (“Non-Profit GAP”). The Office of Administrative Law approved the Policy and it is now codified in the California Code of Regulations under Title 17, Division 4, Chapter 5, Section 100500. This Policy states the rights and responsibilities of academic and non-profit recipients of CIRM research funding. Principal investigators, program directors, and organizational officials with grants management responsibilities may refer to pertinent sections for answers to questions that arise concerning the award and administration of the grants. By accepting a CIRM grant award, grantees agree to comply with the provisions set forth in the policies for the entire project period of the grant, and thereafter.

The proposed amendments to the Non-Profit GAP include non-substantive changes without regulatory effect, changes made for clarity and substantive changes. The proposed amendments in this rulemaking action interpret, clarify and make specific the regulations in Section 100500.

The amendments are to the document incorporated by reference through subdivision (a) of Section 100500 entitled “CIRM Grants Administration Policy for Academic and Non-Profit Institutions” with a footer that now dates the document as “Non-Profit and Academic Institution Grants Administration Policy – OAL Approved – Eff. 3/30/07”. The amendment to subdivision (a) of Section 100500 will now reference a footer that dates the document as “Non-Profit and Academic Institution Grants Administration Policy – July 15, 2008.”

DISCLOSURES REGARDING THE PROPOSED AMENDMENTS:

CIRM has made the following initial determinations:

Mandate on local agencies and school districts: None.

Technical, Theoretical or Empirical Studies, Reports or Documents: None.

Submittal of Comments:

Any interested party may present comments in writing about the proposed amendments to the agency contact person named in this notice. Written comments must be received no later than 5:00 p.m. on September 22, 2008. Comments regarding this proposed action may also be transmitted via e-mail to NonprofitGAP@cirm.ca.gov or by facsimile transmission to (415) 396-9141.

Public Hearing:

CIRM will hold a public hearing starting at 11:00 a.m. on September 22, 2008, at CIRM offices located at 210 King Street, San Francisco, California 94107. At the hearing, any person may present statements or arguments orally or in writing relevant to the proposed amendments.

Effect on Small Business:

CIRM has determined that the proposed amendment will have no impact on small businesses. The regulation implements conditions on awarding and administering grants for stem cell research. This research is conducted almost exclusively by large public and private nonprofit institutions. As such, the amendments to the regulation are not expected to adversely impact small business as defined in Government Code Section 11342.610.

Impact on Local Agencies or School Districts:

CIRM has determined that the proposed amendments do not impose a mandate on local agencies or school districts, nor do they require reimbursement by the state pursuant to Part 7 (commencing with Section 17500) of Division 4 of the Government Code because the amendments do not constitute a “new program or higher level of service of an existing program” within the meaning of Section 6 of Article XIII of the California Constitution. CIRM has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from the proposed amendments.

Costs or Savings to State Agencies:

CIRM has determined that no savings or increased costs to any agency will result from the proposed amendments.

Effect on Federal Funding to the State:

CIRM has determined that no costs or savings in federal funding to the state will result from the proposed amendments.

Effect on Housing Costs:

CIRM has determined that the proposed amendments will have no effect on housing costs.

Significant Statewide Adverse Economic Impact Directly Affecting Businesses:

CIRM has made an initial determination that the proposed amendments will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California Businesses to compete with businesses in other states.

Cost Impacts on Representative Private Persons or Businesses:

CIRM has made an initial determination that the adoption of these amendments will not have a significant cost impact on representative private persons or businesses. CIRM is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed amendments.

Impact on the Creation, Elimination, or Expansion of Jobs:

CIRM has made an initial determination that it is unlikely the proposed amendments will impact the creation or elimination of jobs, the creation of new businesses or the elimination of existing businesses, or the expansion of businesses currently doing business within the State of California.

Consideration of Alternatives:

In accordance with Government Code Section 11346.5, subdivision (a)(13), CIRM must determine that no reasonable alternative it considered, or that has otherwise been identified and brought to its attention, would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons or businesses than the proposed regulatory action. CIRM invites interested persons to present statements or arguments with respect to alternatives to the proposed amendments at the scheduled hearing or during the written comment period.

Availability of Statement of Reasons and Text of Proposed Regulations:

CIRM has prepared an Initial Statement of Reasons, and has available the express terms of the proposed amendments, all of the information upon which the amendments are based, and a rulemaking file. A copy of the Initial Statement of Reasons and the proposed text of the regulation may be obtained from the agency contact person named in this notice. The information upon which CIRM relied in preparing this proposal and the rulemaking file are available for review at the address specified below.

Availability of Changed or Modified Text:

After holding the hearing and considering all timely and relevant comments, CIRM may adopt the proposed amendments substantially as described in this notice. If CIRM makes modifications that are sufficiently related to the originally proposed text of the amendments, it will make the modified text (with the changes clearly indicated) available to the public for at least 15 days before it adopts the regulations as amended. Requests for the modified text should be

addressed to the agency contact person named in this notice. CIRM will accept written comments on any changes for 15 days after the modified text is made available.

Agency Contact:

Written comments about the proposed regulatory action; requests for a copy of the Initial Statements of Reasons, the proposed text of the amendments; and inquiries regarding the rulemaking file may be directed to:

Cynthia Schaffer
California Institute for Regenerative Medicine
210 King Street
San Francisco, CA 94107
(415) 396-9241

Scott Tocher
California Institute for Regenerative Medicine
210 King Street
San Francisco, CA 94107
(415) 396-9136

Questions on the substance of the proposed regulatory action may be directed to:

Amy Lewis, Grants Management Officer
California Institute for Regenerative Medicine
(415) 396-9110

The Notice of Proposed Regulatory Amendment, the Initial Statement of Reasons and any attachments, and the proposed text of the amendments and existing regulation are also available on CIRM's website, www.cirm.ca.gov.

Availability of Final Statement of Reasons:

Following its preparation, a copy of the Final Statement of Reasons mandated by Government Code Section 11346.9, subdivision (a), may be obtained from the contact person named above.

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